# Small Business Guide to FDA

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## INTRODUCTION

The Food and Drug Administration (FDA) recognizes that dealing with a large organization can frequently be a time consuming, frustrating experience. Although there is no acceptable panacea, FDA has instituted a number of activities aimed at easing this problem for regulated small businesses. These include the establishment of the Division of Small Manufacturers Assistance (DSMA) in the Center for Devices and Radiological Health, Small Business Assistance Programs in the six FDA field offices, and the creation of special units in each of the Centers. These units provide technical assistance to small companies, hold exchange meetings to hear the views and perspectives of small businesses, conduct educational workshops, develop informational materials, and provide an accessible, efficient channel through which small businesses can acquire information from the FDA. The primary purpose of these activities is to increase our communication with the small business community. This, in turn, opens the door for improved understanding and a better working relationship. Because FDA regulates a wide range of products - from aspirin to x-ray equipment - we could not tailor this booklet to exactly fit everyone's operation. Instead, we have compiled some basic yet important information about FDA, that, when put to use, will facilitate your interactions with the Agency. If you want to know about FDA's organization, procedures, policies, and regulations, we suggest that you keep this booklet handy. It contains a lot of good information for firms like yours.

# THE FEDERAL REGISTER - WHAT IT IS AND HOW TO USE IT

The Federal Register is one of the most important sources for information on what FDA -- or for that matter, what any government agency is doing. Published daily, Monday through Friday, the Federal Register carries all proposed and finalized regulations and many significant legal notices issued by the various agencies, as well as presidential proclamations and executive orders. Subscriptions to the Federal Register can be purchased from the Superintendent of Documents. For price and order information, call (202) 512-1806 or (202) 512-1530 for online subscriptions. As an alternative, copies can usually be found in local libraries, county courthouses, or federal buildings. The following are examples of how the Federal Register can be used to keep informed of FDA issues and activities:

**ADVANCE NOTICE** - Often, FDA will publish "Notices of Intent" in the Federal Register to give you the earliest possible opportunity to participate in its decisions. These notices inform you that FDA is considering an issue and that your views are welcome before a formal proposal is made.

**PROPOSED REGULATIONS** - When a formal proposal is developed, FDA publishes a "Notice of Proposed Rulemaking" in the Federal Register. The notice also informs you how much time you have to submit written comments about the proposed action. If you do not feel you have enough time to study the proposal and comment on it, you can request, in writing, that Agency officials extend the comment period. If FDA extends the period, a notice of the extension will be published in the Federal Register. Occasionally, a second or third proposal is published in the Federal Register because of the nature of the comments received. Each time a proposal is substantively revised or amended, a notice is published in the Federal Register.

**FINAL REGULATIONS** - Ultimately, a "Final Rule" is published, and the rule specifies the date when the new regulatory requirements or regulations become effective.

**REGULATORY AGENDA** - Twice a year -- in April and October - FDA, along with the entire Department of Health and Human Services, publishes an agenda in the Federal Register that summarizes policy-significant regulations, regulations that are likely to have a significant economic impact on small entities, and other actions under development. This agenda will help you identify actions of interest early to plan your participation. Each item listed includes the name, address and telephone number of an Agency official to contact if you need more information.

**MEETINGS AND HEARINGS** - Notices are published in the Federal Register announcing all meetings of the Agency's advisory committees (see public hearings) and all public meetings that provide an information exchange between FDA and industry, health professionals, consumers, and the scientific and medical communities. The notice contains the date, time and place of the meeting, as well as its agenda. The Federal Register also announces administrative hearings before the Agency and public hearings to gain citizen input into Agency activities (see citizen

petition). Information about meetings of advisory committees is also available by calling (1-800) 741-8138.

## HOW TO COMMENT ON PROPOSED REGULATIONS

Before you comment on regulations proposed by FDA, you may obtain more information about a proposal by contacting the person designated in the Federal Register statement. Whether you agree or disagree with the proposed regulations, you will want to communicate your comments in the most effective way possible. The following points will help you do this:

- Give the title, date of publication, and docket number for the proposal.
- State who you are and how the proposal affects you. (Economic costs and back-up data are more compelling than generalities.)
- Give supporting statements for your position and present new data and scientific findings, if possible.
- Whether you agree or disagree, you may suggest alternatives to the proposal or to requirements that are part of the proposal.
- The more substantive your comments, the more weight they will carry. The same thing is true for petitions (see petition content and format). When FDA considers comments from the public, it's not a simple matter of counting up "for" or "against" options.

Comments on proposed regulations should always be forwarded to Dockets Management Branch, Room 10-61, 5630 Fishers Lane, Rockville, MD 20857; (301) 827-6860

## HOW TO OBTAIN AGENCY DOCUMENTS

has been replaced by

## A Handbook for Requesting Information and Records from FDA (BG 97-6)

## HOW TO OBTAIN FDA STATUTES AND REGULATIONS

Among the statutes enforced by FDA are: the Federal Food, Drug, and Cosmetic Act, as Amended; sections of the Public Health Service Act pertaining to biological products; the Radiation Control for Health and Education Act; the Safe Medical Devices Act; the Mammography Quality Standards Act; the Fair Packaging and Labeling Act; the Infant Formula Act; the Nutrition Labeling and Education Act; and the Dietary Supplement Health and Education Act. These are compiled in one booklet, "Federal Food, Drug, and Cosmetic Act as Amended and Related Laws," which is available from the Superintendent of Documents.
The regulations over which FDA has jurisdiction are codified under Title 21, Code of Federal Regulations (CFR). These are updated on April 1 of each year and are available for sale approximately four months later. Nine volumes are applicable to FDA and may be purchased singly or as a set from the Superintendent of Documents. These regulations are accessible on the Internet at http://www.access.gpo.gov/nara/cfr/cfr-table-search.html. The contents of each volume are listed below:

- Parts 1 to 99. General regulations for the enforcement of the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act. Color additives.
- Parts 100 to 169. Food standards, good manufacturing practice for foods, low-acid canned foods, acidified foods, and food labeling.
- Parts 170 to 199. Food additives.
- Parts 200 to 299. General regulations for drugs.
- Parts 300 to 499. Drugs for human use.
- Parts 500 to 599. Animal drugs, feeds, and related products.
- Parts 600 to 799. Biologics and cosmetics.
- Parts 800 to 1299. Medical devices and radiological health. Regulations under the Federal Import Milk Act, the Federal Tea Importation Act, the Federal Caustic Poison Act, and for control of communicable diseases and interstate conveyance sanitation.
- Parts 1300 through end. Drug Enforcement Administration regulations and requirements.

## "REQUIREMENTS OF LAWS AND REGULATIONS ENFORCED BY THE U.S. FOOD AND DRUG ADMINISTRATION"

"Requirements of Laws and Regulations Enforced by the U.S. Food and Drug Administration" is an easy-to-read booklet summarizing FDA requirements. Single copies are available at no charge by writing to: Office of Consumer Affairs (HFE-88), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

# HOW TO PETITION THE FDA

Anyone may request or petition FDA to change or create an Agency policy or regulation under 21 CFR Part 10.30. If you believe this type of action is necessary, direct your request to FDA's Dockets Management Branch http://www.fda.gov/ohrms/dockets/. When submitting a petition, keep these points in mind:

- Clearly state what problem you think the Agency needs to address.
- Propose specifically what the Agency's action should be. Your proposal should be based on sound, supportable facts.
- Submit the petition, an original and three (3) copies, unless otherwise stipulated in the Federal Register announcement, to:

Food and Drug Administration
Dockets Management Branch
Room 10-61
5630 Fishers Lane
Rockville, MD 20857
(301) 827-6860

FDA carefully considers every petition and must respond within 180 days by either approving or denying it, or providing a tentative response indicating why FDA has been unable to reach a decision. If FDA approves the petition, it may be published in the Federal Register. Your petition could eventually be incorporated into Agency policy. An example showing how to prepare a citizen's petition follows:

**Petition Content and Format**

(Date) _____
Dockets Management Branch, Food and Drug Administration, Department of Health and Human Services, Room 10-61, 5630 Fishers Lane, Rockville, MD 20857.
CITIZEN PETITION
The undersigned submits this petition under _____ (relevant statutory sections, if known) of the _____ Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs (under 21 CFR, Part 5.10) to request the Commissioner of Food and Drugs to _____(issue, amend, or revoke a regulation or order to take or refrain from taking any other form of administrative action).

A. ACTION REQUESTED

1. . If the petition requests the Commissioner to issue, amend or revoke a regulation, give the exact wording of the existing regulation (if any) and the proposed regulation or amendment requested.

2. . If the petition requests the Commissioner to issue, amend or revoke an order, include a copy of the exact wording of the citation to the existing order (if any) and the exact wording requested for the proposed order.
3. . If the petition requests the Commissioner to take or refrain from taking any other form of administrative action, state the specific action or relief requested.

B. STATEMENT OF GROUNDS
Include a well organized statement of the factual and legal grounds upon which the petition is based. Opposing views known to the petitioner should be presented.

C. ENVIRONMENTAL IMPACT STATEMENT
Give an environmental impact analysis report in the form specified in 21 CFR, Part 25.1(g), except for the types of actions specified in 21 CFR, Part 25.1(d).

D. ECONOMIC IMPACT STATEMENT
The following information is to be submitted only when requested by the Commissioner following review of the petition: a statement of the effect of the requested action on 1) cost (and price) increases to industry, government, and consumers; 2) productivity of wage earners, businesses, or government; 3) competition; 4) supplies of important materials, products, or services; 5) employment; and 6) energy supply or demand.

The undersigned certifies that, to the best of his/her knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

_____ _____

(Signature) Name of Petitioner

_____

(Mailing Address)

_____

(Phone)

# HOW TO PARTICIPATE IN AGENCY DECISION-MAKING

In addition to commenting on Federal Register documents and petitioning the Agency, there are a number of ways that can interact with FDA to make your viewpoint known. Here are a few examples:

**Public Meetings or Conferences**
FDA uses public meetings and conferences to discuss significant issues with the public. The Agency may schedule public meetings, sometimes referred to as "exchange meetings," before developing a proposal, or after proposing a program change. The meetings offer a chance for you and FDA managers to discuss issues informally before the rulemaking process begins. FDA announces meetings in the Federal Register and trade publications.

**Industry Information/Education Meetings**
Many meetings and workshops are conducted in which key representatives from industry, government, academia, and professional, consumer, ethnic, and patient groups discuss subjects of vital concern to industry and the FDA.

**Public Hearings**
A hearing is an opportunity for you to take part in a rule-making proceeding. FDA always announces hearings in the Federal Register and usually in other publications (e.g., industry newsletters) related to the topic of the hearing. Depending on the subject of the hearing, you can testify on specific issues that are included in an Agency proposal, or you can present your views about general issues on Agency programs. At all hearings, your testimony, whether it is presented orally or in writing, will become part of an official record of evidence which will help the Agency make policy decisions.

**Public Advisory Committees and Panels**
FDA routinely looks for qualified people to serve on a variety of public advisory committees and panels. Many of the Agency's committees and panels include members representing consumer and industry interests. FDA requests nominations for these members through announcements in the Federal Register. The committees generally study current scientific work and make recommendations to the Agency on product approvals, regulations, and other actions. Membership on most committees requires a scientific background. A free copy of "FDA Public Advisory Groups" or further information about FDA advisory committees, can be obtained by contacting the Office of Committee Management (HFA-306), Food and Drug Administration, Room 4B-17, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857; (301) 827-5496 or fax (301) 827-5891. For current information or information updates on FDA advisory committee meetings, call the Advisory Committee Information Line by dialing (1-800) 741-8138 or (301) 443-0572, and the five digit number assigned to each advisory committee. This number will appear in each notice of meeting.

**How Regulated Industry Can Communicate with FDA**
[http://www.fda.gov/opacom/7indust.html] Main FDA Address and Phone Number (for general inquiries):

U.S. Food and Drug Administration
(HF-40)
Rockville, MD 20857
Phone: 301-827-4450)
Fax: 301-443-1863

## WHAT TO DO WHEN

**Marketing a New Product**
FDA must give the manufacturer, distributor or importer clearance to market certain products before they can be sold in interstate commerce. For example:

- New human and veterinary drugs ["New" drugs = those with new intended uses or new chemical entities] and certain medical devices [examples = wheelchair, contact lens, heart pacemaker] must be approved for safety and effectiveness, and their labeling reviewed for accuracy and thoroughness.
- Substances added to food must meet the requirements of the food additive regulations that are based on FDA's review of scientific data of safety and utility that have been submitted to FDA.
- Manufacturers of low-acid canned foods* packaged in air- tight bottles, plastic bags, and cans and acidified foods** must register with FDA and submit detailed information about heat-treatments to destroy bacteria (and acidification, if necessary to prevent growth of bacterial spores).
- Specific premarket controls apply to biological products that are required to be licensed under Federal law.

Marketing these kinds of products or conducting experimental investigations with them in human clinical trials, requires that one or more applications be filed with FDA and that certain procedures be followed.

In addition, although some products [such as cosmetics and some radiation-emitting items] do not need premarket approval from FDA, there are regulatory standards and regulations applicable to their manufacture and labeling that fall under FDA's jurisdiction. Therefore, to avoid unnecessary delay in bringing new products to market, it would be helpful to talk with an FDA product specialist early in your planning. (See Who to Contact for Assistance for the most appropriate contact).

**PRODUCTS THAT REQUIRE REGISTRATION AND LISTING, FILING OF A COOKING PROCESS, OR LICENSING PRIOR TO MARKETING:**

- Low Acid Canned Foods [LACF]* such as traditional vegetables, or any other food requiring aseptic processing to control the growth of pathogens [To order forms 2541 or 2541c via phone: 202-205-5282]
- Acidified Foods** such as salsas, hot sauces, certain salad dressings, relishes, barbecue sauces, or any other food that use acidification [addition of vinegar, lemon juice, etc.] to control the growth of pathogens [To order forms 2541 or 2541a via phone: 202-205-5282]
- Drugs including medical gases, human and veterinary prescription drugs, over-the-counter [OTC] drugs, and certain biologics [To order forms 2656, 2657, or 2658 via phone: 301-594-1086]
    - **In addition,** many drugs require an Investigational New Drug [IND] application, New Drug Application [NDA]**,** an Abbreviated New Drug Application [ANDA]**,** New Animal Drug Application [NADA]**,** or an Abbreviated New Animal Drug Application [ANADA]. [To order forms via phone: 301-827-3937]*
- Devices - human and animal devices [To order forms 2891 or 2892 via FAX: 301-443-8818]
    - **In addition,** many devices require Premarket Notification [510(k)] or Premarket Approval [PMA]
- Biologics and Blood Banks - human biologics may also be considered a drug or device and subject to the requirements of a drug or device. [Phone for forms: 301-827-3546]* USDA regulates biologics for animals.

*Some forms only available by mail from [NO phone/fax orders]:

Consolidated Forms and Publications Distribution Center [CFPDC]
Washington Commerce Center
3222 Hubbard Road
Landover, MD 20785

For general information about FDA requirements and procedures for all products it regulates see the "FDA BLUE BOOK" (a.k.a. "Requirements of Laws and Regulations Enforced by the Food and Drug Administration" *Last Updated 1998.) Note: The passage of the Food and Drug Administration Modernization Act [FDAMA] in 1997 effected significant changes for many FDA-regulated products. Please refer to this document on the* FDAMA Home Page**.**

**Handling an FDA Inspection**

FDA may conduct an inspection of your operation for a variety of reasons, such as a routinely scheduled investigation, a survey, or a response to a reported problem. The investigator will present his/her credentials and "Notice of Inspection" upon arriving at your plant. A knowledgeable person in your firm, such as the plant or production manager, preferably designated ahead of time, should accompany the investigator at all times. It is in your best interest to fully understand FDA's inspection procedures. When you are unsure of certain actions taken by the investigator, don't hesitate to ask questions.

Usually, he/she will examine your production process, look at certain records and collect samples. At the conclusion of the inspection, the investigator will discuss with your firm's management his/her findings and concerns; however, he/she will not usually recommend specific corrective measures. He/she will leave with your management a written report of any conditions or practices, which, in his/her judgment, indicate objectionable conditions, or practices. This list of "Inspectional Observations", also called an FDA-483, can be used by your firm's management as a guide for corrective action. Your firm can and should respond to the FDA-483 during the discussion with the investigator. In fact, corrective actions or procedural changes that were accomplished immediately in the presence of the investigator are regarded as positive indications of your concern and desire to voluntarily correct discrepancies.

If you do not agree with the actions being taken by the FDA or if you have a question about the jurisdiction of the agency in a particular matter, you can contact the FDA's Office of the Ombudsman to seek a resolution.

- Office of the Ombudsman
  Food and Drug Administration
  5600 Fishers Lane
  Room 14B03, HF-7
  Rockville, MD 20857
  Telephone: 301-827-3390
  Fax: 301-480-8039
  E-mail: ombudsma@oc.fda.gov *[Sending confidential information by electronic mail is not recommended.]*

See the FDA Center Small Business Contacts for the Ombudsman in the various FDA Centers. *If FDA takes regulatory action against your firm, the Small Business Representatives are not available for guidance, since their activities are nonregulatory in nature.* You should contact a district Compliance Officer for advice (see FDA District Offices) under those circumstances.
Recalling Violative Products

A "recall" is a firm's removal or correction of a marketed product that FDA considers to be in violation of the laws it administers and against which FDA would initiate legal action; e.g., warning letter, seizure, etc.

During a recall, a firm can expect to work more closely with FDA than under almost any other circumstance. In fact, the first step, when a product must be recalled, is for the manufacturer or distributor to call the nearest FDA field office and talk with the Recall Coordinator. See list of FDA District Offices.

FDA's main concerns during a recall are that the firm has determined the location of the product and organized the prompt removal from commerce of any suspect lots. FDA will then work with the firm to identify the cause of the problem and the corrections needed to prevent a recurrence. FDA is also concerned about the final disposition of the recalled product. Final disposition may be in the form of destruction, with appropriate regard for local laws concerning waste removal or incineration. Other possible conclusions to recalls include reconditioning (relabeling, repacking, reworking, etc.) or exportation, if permitted. Any method used must first be discussed with the FDA District Office, as FDA may wish to witness the effort, and the firm must maintain proper documentation.

Also with device recalls, the firm must report to the FDA District Office any Corrections or Removals under the new regulations (21 CFR 806.10c) as soon as the firm becomes aware of the problem.

Essentially, the procedures for a product recall are determined by the individual company; however, a proper recall system will include provisions for record-keeping, handling product returns, liaison with FDA, and public information. The efficiency of tracking and removing a product depends on the completeness of the records maintained throughout the production and distribution process.

Information on Recalls of FDA Regulated Products:
http://www.fda.gov/ora/compliance_ref/recalls/recallpg.html

Professional Demeanor of FDA Employee:
If you are concerned about the professional demeanor of any FDA employee during an inspection or during their performance of other official duties, you should contact the District Director in the nearest FDA field office to resolve your concerns. See LIST OF DISTRICT DIRECTORS.

# WHO TO CONTACT FOR ASSISTANCE

Knowing whom to contact is the first step in obtaining information you need. It may be helpful to keep in mind that FDA has five Centers, five Regions, and 21 District Offices within those regions. Reaching the right office and, more importantly, the right person who has the information you need, can sometimes be frustrating. This list of contacts should help guide you in the right direction.

Whether you need information related to getting your product approved and on the market, wanting an FDA speaker for your industry meeting, or just need copies of FDA regulations, there are a number of sources to which you can go for general assistance:
Small Business Representatives (SBRs) - FDA has Small Business Representatives who help small businesses whose products are regulated by FDA. They are located in five regions of the country: New York, Philadelphia, Atlanta, Dallas, and Oakland.

**OTHER LINKS WITH INFORMATION OR ASSISTANCE FOR INDUSTRY:**

DRUGS - [CDER] - http://www.fda.gov/CDER/about/smallbiz/default.htm
FOODS, DIETARY SUPPLEMENTS, COSMETICS - [CFSAN] - http://vm.cfsan.fda.gov/~comm/foodbiz.html
DEVICES - [DSMA in CDRH] - http://www.fda.gov/cdrh/dsma/dsmamain.html or "DEVICE ADVICE" - http://www.fda.gov/cdrh/devadvice/11.html
BIOLOGICS - [CBER] - http://www.fda.gov/CBER/sitemap.htm
ANIMAL PRODUCTS - [CVM] - http://www.fda.gov/cvm/fda/mappgs/faqs.html

These sites are available to deal with the special concerns and/or provide helpful information to small firms and new businesses. They provide information that clarifies how Agency laws and regulations apply to various products or specific circumstances and suggest methods of meeting these requirements. The SBRs can respond to your inquiries, conduct or participate in workshops and conferences, or visit your plant, at your request, to offer assistance.
All FDA speaker requests must be submitted through:

Food and Drug Administration
Office of Public Affairs
Program and Speaker Coordination Staff
5600 Fishers Lane, Room 15A-08
Rockville, MD 20857
FAX 301-827-2823

# SMALL BUSINESS REPRESENTATIVES (SBRs)

Small Business Representative (HFR-NEl7) Vacant
FDA, Northeast Region (CT, MA, ME, NH, NY, RI, VT)
158-15 Liberty Avenue
Jamaica, NY 11433-1034
ph (718) 662-5618
fax (718) 662-5434
Email: oranersbr@ora.fda.gov

Small Business Representative (HFR-CE17) Marie T. Falcone
FDA, Central Region (DC, DE, IL, IN, KY, MD, MI, MN, ND, NJ, OH, PA, SD, VA, WI, WV)
U.S. Customhouse
2nd and Chestnut Sts., Room 900
Philadelphia, PA 19106
ph (215) 597-2120, ext. 4003
fax (215) 597-5798
Email: mfalcone@ora.fda.gov

Small Business Representative (HFR-SE17) Vacant
FDA, Southeast Region (AL, FL, GA, LA, MS, NC, PR, SC, TN, VI)
60 Eighth St., N.E.
Atlanta, GA 30309
ph (404) 253-2238
fax (404) 253-1207
Email: orasesbr@ora.fda.gov

Small Business Representative, (HFR-SW17) David Arvelo
FDA, Southwest Region (AR, CO, IA, KS, MO, NE, NM, OK, TX, UT, WY)
7920 Elmbrook Dr., Suite 102
Dallas, TX 75247
ph (214) 655-8100, ext. 133
fax (214) 655-8114
Email: oraswrwbr@ora.fda.gov

Small Business Representative, (HFR-PA17) Marcia Madrigal
FDA, Pacific Region (AK, AZ, CA, HI, ID, MT, NV, OR, WA)
Oakland Federal Building
1301 Clay Street, Suite 1180-N
Oakland, CA 94612-5217
ph (510) 637-3980
fax (510) 637-3977
Email:mmadriga@ora.fda.gov

# REGIONS AND DISTRICTS
# FOOD AND DRUG ADMINISTRATION

| REGION and DISTRICT | STATES SERVED | DIRECTOR |
|---|---|---|
| NORTHEAST REGION:<br>New York Regional Office:<br>158-15 Liberty Avenue<br>Jamaica, NY 11433-1034<br>Phone - (718) 662-5416<br>fax - (718) 662-5434 | CT, MA, ME, NH, NY, RI, VT | DIANA J. KOLAITIS<br>REGIONAL DIRECTOR |
| New York District Office<br>158-15 Liberty Avenue<br>Jamaica, N.Y. 11433-1034<br>Phone - (7l8) 662-5447<br>fax - (718) 662-5665 | NY | Vacant<br>District Director |
| New England District Office<br>One Montvale Ave.<br>Stoneham, MA 02180<br>Phone - (78l) 279-l675<br>fax - (78l) 279-l742 | CT, MA, ME, NH, RI, VT | Gail T. Costello<br>District Director |
| CENTRAL REGION:<br>Philadelphia Regional Office<br>U.S. Customhouse<br>2nd and Chestnut Sts., Room 900<br>Philadelphia, PA 19106<br>Phone - (2l5) 597-4390<br>fax - (215) 597-5798 | DC, DE, IL, IN, KY, MD, MI, MN, ND, NJ, OH, PA, SD, VA, WI, WV | SUSAN M. SETTERBERG<br>REGIONAL DIRECTOR<br><br>Joseph X. Phillips<br>Deputy Regional Director |
| Philadelphia District Office<br>U.S. Customhouse<br>2nd and Chestnut Sts., Room 900<br>Philadelphia, PA 19106<br>Phone - (215) 597-4390<br>fax - (215) 597-4660 | DE, PA | Thomas Gardine<br>District Director |
| Central Regional Office - Chicago<br>20 North Michigan Ave. Suite 510<br>Chicago, IL 60602<br>Phone - (312) 353-9400<br>fax - (312) 886-1682 | DC, DE, IL, IN, KY, MD, MI, MN, ND, NJ, OH, PA, SD, VA, WI, WV | Andy Bonanno<br>Deputy Regional Director |

| REGION and DISTRICT | STATES SERVED | DIRECTOR |
|---|---|---|
| Chicago District Office<br>300 S. Riverside Plaza, 5th Floor<br>Suite 550 South<br>Chicago, IL 60606<br>Phone - (312) 353-7379<br>fax - (312) 886-3280 | IL | Raymond V. Mlecko<br>District Director |
| Baltimore District Office<br>900 Madison Ave<br>Baltimore, MD 21201-2199<br>Phone - (410) 962-4012<br>fax - (410) 962-0044 | DC, MD, VA, WV | Lee Bowers<br>District Director |
| Cincinnati District Office<br>6751 Steger Drive<br>Cincinnati, OH 45237-3097<br>Phone - (513) 679-2700<br>fax - (513) 679-2771 | KY, OH | Henry Fielden<br>District Director |
| New Jersey District Office<br>Waterview Corporate Center<br>10 Waterview Blvd., 3rd Floor<br>Parsippany, NJ 07054<br>Phone - (973) 526-6000<br>fax - (973) 526-6069 | NJ | Douglas I. Ellsworth<br>District Director |
| Detroit District Office<br>1560 E. Jefferson Ave.<br>Detroit, MI 48207-3l79<br>Phone - (313) 226-6260<br>fax - (313) 226-3076 | IN, MI | Raymond V. Mlecko<br>District Director |
| Minneapolis District Office<br>240 Hennepin Ave.<br>Minneapolis, MN 55401-l9l2<br>Phone - (612) 334-4100<br>fax - (612) 334-4134 | MN, ND, SD, WI | James A. Rahto<br>District Director |
| SOUTHEAST REGION:<br>Atlanta Regional Office<br>60 Eighth St. N.E.<br>Atlanta, GA 30309<br>Phone - (404) 253-1171<br>fax - (404) 253-1207 | AL, FL, GA, LA, MS,<br>NC, PR, SC, TN, VI | GARY J. DYKSTRA<br>REGIONAL DIRECTOR |

| REGION and DISTRICT | STATES SERVED | DIRECTOR |
|---|---|---|
| Atlanta District Office<br>60 Eighth St. N.E.<br>Atlanta, GA 30309<br>Phone - (404) 253-1161<br>fax - (404) 253-1202 | GA, NC, SC | Ballard H. Graham<br>District Director |
| New Orleans District Office<br>6600 Plaza Drive Suite 400<br>New Orleans, LA 70127<br>Phone - (504) 240-2401<br>fax - (504) 240-6360 | AL, LA, MS, TN | Carl Draper<br>District Director |
| Florida District Office<br>555 Winderly Place. Suite 200<br>Maitland, FL 3275l<br>Phone - (407) 253-1161<br>fax - (407) 253-1202 | FL | Emma R. Singleton<br>District Director |
| San Juan District Office<br>466 Fernandez Juncos Avenue<br>San Juan, PR 00901-3223<br>Phone - (787) 729-6842<br>fax - (787) 729-6809 | PR, VI | Millie Barber<br>District Director |
| SOUTHWEST REGION:<br>Dallas Regional Office<br>7920 Elmbrook Dr. ,Suite l02<br>Dallas, TX 75247-4982<br>Phone - (214) 655-8100<br>fax - (214) 655-8130 | AR, CO, IA, KS, MO, NE, NM, OK, TX, UT, WY | GARY PIERCE<br>REGIONAL DIRECTOR |
| Dallas District Office<br>33l0 Live Oak 3rd Floor<br>Dallas, TX 75204<br>Phone - (214) 655-5315<br>fax - (214) 655-5331 | AR, OK, TX | Michael A. Chappell<br>District Director |
| Southwest Import District<br>3310 Live Oak 3rd Floor<br>Dallas, TX 75204<br>Phone - 214 655-5310<br>Toll-free - 800-991-4881<br>fax - 214-655-5330 | AR, AZ, CA, CO, IA, KS, MO, NE, NM, OK, TX, UT, WY | Robert Deininger<br>District Director |

| REGION and DISTRICT | STATES SERVED | DIRECTOR |
|---|---|---|
| Denver District Office<br>6th & Kipling Sts., Denver Federal Ctr<br>Bldg. 20, Entrance W-l0<br>Denver, CO 80225-0087<br>Phone - (303) 236-3000<br>fax - (303) 236-3099<br>(Mailing Address:<br>P.O. Box 25087<br>Denver, CO 80225-0087) | CO, NM, UT, WY | Tom Allison<br>District Director |
| Kansas City District Office<br>11510 West 80th St.<br>Lenexa, KS 66214<br>Phone - (913) 752-2144<br>fax - (913) 752-2136<br>(Mailing Address:<br>P.O. Box 15905<br>Lenexa, KS 66285-5905) | IA, KS, MO, NE | Charles W. Sedgwick<br>District Director |
| PACIFIC REGION:<br>Oakland Regional Office<br>Oakland Federal Building<br>1301 Clay St. Suite 1180 - N<br>Oakland, CA 94612-5217<br>Phone - (510) 637-3960<br>fax - (510) 637-3976 | AK, AZ, CA, HI, ID, MT, NV, OR, WA | BRENDA HOLMAN<br>REGIONAL DIRECTOR |
| Los Angeles District Office<br>l9900 Mac Arthur Blvd, Suite 300<br>Irvine, CA 92612<br>Phone - (949) 798-7600<br>fax - (949) 798-7690 | AZ ,CA | Alonza E. Cruse<br>District Director |
| Seattle District Office<br>22201 23rd Dr. S.E.<br>Bothell, WA 98021<br>Phone - (425) 486-8788<br>fax - (425) 483-4996 | AK, ID, MT, OR, WA | Charles Breen<br>District Director |
| San Francisco District Office<br>1431 Harbor Bay Parkway<br>Alameda, CA 94502<br>Phone - (510) 337-6700<br>fax - (510) 337-6859 | CA, HI, NV | Vacant<br>District Director |

# FDA CENTERS' SMALL BUSINESS CONTACTS

Center Small Business Contact Person - When you have an inquiry that requires highly specialized assistance, such as information to be submitted in a new drug application, or if you are requesting a meeting with someone in headquarters, you may save time by directly calling the small business contact person in the appropriate center. The people listed below can also send you a wide variety of informational materials or audiovisuals:

Center for Drug Evaluation and Research
Office of Training and Communication (HFD-210)
Ron Wilson, Director
Small Business Assistance
Drug Information Branch
E-mail dib@cder.fda.gov
5600 Fishers Lane, Room 12B31
Rockville, MD 20852
Phone - (301) 827-4573
Fax on Demand - (800) 342-2722

CDER Ombudsman
James C. Morrison
Phone - 301-594-5443
Fax - 301-594-5298
E-mail - MORRISONJ@CDER.FDA.GOV

Center for Biologics Evaluation and Research
Lorrie McNeill, Team Leader, mcneill@cber.fda.gov
Division of Manufacturers Assistance and Training (HFM-42), matt@cber.fda.gov
11400 Rockville Pike, Suite 200N
Rockville, MD 20857-0001
Phone - (301) 827-2000
fax 301-827-3079
Voice Information System - (30l) 827-l800 (1-800-835-4709)
Office fax - (30l) 827-3843

CBER Ombudsman
Robert A. Yetter
Phone - 301-827-0373
Fax - 301-827-0440
E-mail - YETTERR@CBER.FDA.GOV

Center for Food Safety and Applied Nutrition
John M. Tisler, Director, jxt@cfsan.fda.gov
Industry Activities Staff (HFS-565)
Room 5425 FOB-8
200 C Street, SW
Washington, DC 20204
Phone - (202) 205-5251
fax - (202) 205-4450

CFSAN Ombudsman
FDA Office of the Ombudsman
Phone - 301-827-3390
Fax - 301-480-8039
Email - ombudsma@oc.fda.gov

Center for Devices and Radiological Health
John F. Stigi, Director, dsma@cdrh.fda.gov
Division of Small Manufacturers Assistance (HFZ-220), www.fda.gov/cdrh/devadvice/
Room 130C
1350 Piccard Dr.
Rockville, MD 20850
Phone - (1-800) 638-2041
fax - (301) 443-8818

CDRH Ombudsman
Les Weinstein
Phone - 301-443-6220
Fax - 301-443-2692
Email - LSW@CDRH.FDA.GOV

Center for Veterinary Medicine
Joanne M. Kla, jkla@cvm.fda.gov
Consumer Safety Officer
Communication Staff (HFV-l2)
Room N428 Metro Park North #2
7500 Standish Place
Rockville, MD 20855-2773
Phone - (301) 827-6507
fax - (301) 594-4512

CVM Ombudsman
Marcia K. Larkins
Phone - 301-594-1830
Fax - 301-827-0137
E-mail - mlarkins@cvm.fda.gov

In addition, the Division of Small Manufacturers Assistance (DSMA), established in the Center for Devices and Radiological Health, provides technical and other non-financial assistance to small medical device manufacturers. Although DSMA personnel are located in headquarters, they routinely provide field assistance to firms by conducting workshops and, at the request of the manufacturer, making onsite visits.

Small Business Assistance for drug firms can be accessed from the Center for Drug Evaluation and Research at http://www.fda.gov/cder/about/smallbiz/default.htm or by calling the Drug Information Branch, listed above

## HOW TO OBTAIN ASSISTANCE FOR FDA'S PROCUREMENT AND CONTRACT ACTIVITIES

FDA has a special program that helps small companies participate in the Agency's procurement and contract activities. The program's goal is to seek out and encourage small companies to provide the Agency with needed supplies and services.

Procurement activities include the purchase of scientific and laboratory equipment such as chemicals, glassware, furniture, electronic components, various species of laboratory animals, animal feed, bedding, holding cages, and other related supplies.

The Agency also solicits proposals and awards contracts for research, surveys and studies in the areas of management, construction/renovation, science, and medicine.

The Agency has a Small and Disadvantaged Business Utilization Specialist who is available to assist and counsel small companies in capturing the Agency's procurement and contract dollars. Small companies that are interested in obtaining more information about the Agency's procurement and contract activities may direct their inquiries to:

Small and Disadvantaged Business Utilization Specialist
Food and Drug Administration
Office of Facilities, Acquisitions and Central Services, HFA-505
5630 Fishers Lane, Room 2038
Rockville, MD 20857
301-827-6890

**FREQUENTLY CALLED NUMBERS & WEBSITE INDEX**
TOLL-FREE 888-INFO-FDA (888-463-6332)

**CENTER FOR BIOLOGICS EVALUATION AND RESEARCH**
Fax-on-Demand (Documents via fax) TOLL-FREE l-888-223-7329 or 301-827-3844

**CENTER FOR DEVICES AND RADIOLOGICAL HEALTH**
DIVISION OF SMALL MANUFACTURERS ASSISTANCE (DSMA)
TOLL-FREE 1-800-638-2041 or 301-443-6597
CDRH FAX-ON-DEMAND (Documents via fax)
TOLL-FREE 1-800-899-0381 or 301-827-0111

**CENTER FOR DRUG EVALUATION AND RESEARCH**
DRUG INFORMATION LINE 301-827-4573
FAX LINE 301-827-4577

**CENTER FOR FOOD SAFETY AND APPLIED NUTRITION**
SEAFOOD HOTLINE TOLL-FREE l-800-FDA-4010 or 1-800-332-4010 or 202-205-43l4

**OUTREACH AND INFORMATION CENTER** 1-800-332-4010

**NATIONAL INSTITUTES OF HEALTH GRANTS INFORMATION LINE**
(For information about grants involving FDA regulated products) 301-435-0714

**SMALL BUSINESS ADMINISTRATION**
Small Business Answer Desk 1-800-827-5722
409 3rd Street S.W.
Washington, DC 20416 202-606-4000

**SUPERINTENDENT OF DOCUMENTS**
New Orders 202-512-1806
Superintendent of Documents
P.O. Box 37l954
Pittsburgh, PA l5250-7954
for ordering government publications online 202-512-1530

## ACCESS INFORMATION FROM THE INTERNET

World Wide Web (WWW) FDA Home Page can be reached at the Uniform Resource Locator: http://www.fda.gov/ (with hypertext links to information about various FDA responsibilities: foods, human drugs, animal drugs, biologics, cosmetics, medical devices and radiological health, toxicology, and FDA news). FDA is placing the documents that the public most frequently requests on the WWW site to give users more immediate access. Websites Referenced in this document and FDA-related websites:

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| CBER - Biologics Standard Operating Policy and Procedures | http://www.fda.gov/cber/regsopp/8403.htm | license forms, instructions, guidance |
| CBER - Center for Biologics Evaluation and Research | http://www.fda.gov/cber/ | blood, biologic products, tissue, in-vitro diagnostics |
| CBER - Site Map | http://www.fda.gov/CBER/sitemap.htm | links to blood, tissue, and biologics information |
| CDER - ANDA Application Process | http://www.fda.gov/cder/regulatory/applications/ANDA.htm | forms for generic drug submissions, instructions, guidance |
| CDER - Center for Drug Evaluation and Research | http://www.fda.gov/cder/ | prescription human drugs, over-the-counter drugs, medical gases |
| CDER - Drug Registration / Listing | http://www.fda.gov/cder/drls/default.htm | facility registration and drug listing forms, instructions, guidance |
| CDER - IND Application Process | http://www.fda.gov/cder/regulatory/applications/ind_page_1.htm | investigational drug forms, instructions, guidance |
| CDER - NDA Application Process | http://www.fda.gov/cder/regulatory/applications/NDA.htm | forms for new drug submissions, instructions, guidance |
| CDER - Small Business Assistance | http://www.fda.gov/CDER/about/smallbiz/default.htm | assistance for new and small drug businesses |
| CDRH - Center for Devices and Radiological Health | http://www.fda.gov/cdrh/ | human and animal devices, in-vitro diagnostics, radiologicals, lasers |
| CDRH - Device Advice | http://www.fda.gov/cdrh/devadvice/ | device advice, search device databases; 510k / PMA help |
| CDRH - Device Registration / Listing | http://www.fda.gov/cdrh/dsma/rlman.html | forms for facility registration and device listings, instructions, guidance |
| CDRH / DSMA - Division of Small Manufacturers Assistance | http://www.fda.gov/cdrh/dsma/dsmamain.html | assistance for small device businesses |
| CFSAN - Center for Food Safety and Applied Nutrition | http://vm.cfsan.fda.gov/ | food [except red meat and poultry], dietary supplements, food additives, cosmetics, dinnerware |
| CFSAN - LACF / Acidified Food Registration / Process Filing | http://vm.cfsan.fda.gov/~lrd/lacfregs.html | forms for facility registration and filing a cooking process [acidified and low acid canned foods only], instructions, and guidance |
| CFSAN - Starting a Food Business | http://vm.cfsan.fda.gov/~comm/foodbiz.html | information, assistance for new food businesses |
| Compilation of Laws Enforced by Food and Drug Administration | http://www.fda.gov/opacom/laws/lawtoc.htm | access all FDA regulations |

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|---|---|---|
| CVM - Center for Veterinary Medicine | http://www.fda.gov/cvm/ | animal drugs, animal feed, pet products |
| CVM - FAQ's | http://www.fda.gov/cvm/fda/mappgs/faqs.html | Frequently Asked Questions [and Answers] about veterinary regulations |
| CVM - NADA / ANADA Application Process | http://www.fda.gov/cvm/fda/mappgs/nadaappr.htm | forms for new animal drug submissions, instructions, guidance |
| FDA - Citizen Petitions | http://www.fda.gov/opacom/morechoices/smallbusiness/citizpet.html | petition requests to add, remove, or change agency regulations |
| FDA - How Regulated Industry Can Communicate with FDA | http://www.fda.gov/opacom/7indust.html | phone numbers, web links to various agency groups |
| FDA - Ombudsman | http://www.fda.gov/oc/ombudsman/homepage.htm | mediation, resolution of disputes with FDA and help for industry |
| FDA - Petition Content and Format | http://www.fda.gov/opacom/morechoices/smallbusiness/petit.html | format for submitting petition requests |
| FDA - Public Docket of Proposed Regulations | http://www.fda.gov/ohrms/dockets/ | comment on proposed regulations, view pending regulations |
| FDA - Public Hearings | http://www.fda.gov/opacom/morechoices/smallbusiness/pubhear.html | how to participate in FDA's rulemaking process |
| FDA - Recalls | http://www.fda.gov/ora/compliance_ref/recalls/recallpg.html | product recall information, regulations, procedures |
| FDA "Blue Book" | http://www.fda.gov/opacom/morechoices/smallbusiness/ blubook/blubook2.htm | FDA regulations explained in layman's terminology |
| FDA FOI - Handbook for Requesting Information and Records | http://www.fda.gov/opacom/backgrounders/foiahand.html | how to submit requests under the Freedom of Information Act |
| FDA Home Page | http://www.fda.gov/ | starting point for all FDA websites |
| FDAMA | http://www.fda.gov/opacom/7modact.html | changes to FDA regulations since 1997 |
| General Index for Industry | http://www.fda.gov/opacom/morechoices/moreindu.html | FDA-related websites |
| Index of Non-FDA Web Sites | http://www.fda.gov/opacom/websites.html | FDA-related websites |
| State Health Agencies | http://www.fda.gov/oca/sthealth.htm | links to state agencies |
| US Government - Superintendent of Documents | http://www.fda.gov/opacom/morechoices/smallbusiness/supdoc.html | access to all government publications |
| US Government CFR's Online | http://www.access.gpo.gov/nara/cfr/cfr-table-search.html | access to all government regulations that are online |
| USDA - Home Website | http://www.usda.gov/ | red meat, poultry regulations, information |